5

10

15

20

25

Ò

-64-

CLAIMS

What is Claimed is:

- 1. A system for preserving a human or human-compatible harvested organ in need of preservation, resuscitation or evaluation during a preservation period prior to implantation comprising:
 - (a) containment means for containing said organ in communication with a fluid media comprising (i) whole blood or leukocyte-depleted whole blood compatible with said organ and (ii) a preservation solution;
 - (b) delivery means for delivering said fluid media to at least one major vessel of said organ;
 - (c) means for carrying said fluid media away from said organ;
 - (d) temperature control means for maintaining the temperature of said organ at a normothermic temperature of about 20°C to about 37°C;
 - (e) pressure control means for controlling the pressure of said fluid media;
 - (f) oxygenation means for oxygenating at least a part of said fluid media;
 - (g) filtering means for removing unwanted filtrate from said fluid media;
 - (h) flow control means for controlling the flow of at least a part of said fluid media; and
 - (i) means for supplying chemical substances selected from the group consisting of mannitol, dextrose, sodium chloride, potassium chloride, insulin, calcium chloride, sodium bicarbonate, monocarboxylic fatty acids and epinephrine.
- 2. A system according to Claim 1 wherein said fluid media surrounds the exterior of said organ.
 - 3. A system according to Claim 1 wherein said system further includes a divider to separate said fluid media from said organ.



- 4. A system according to Claim 1 wherein said fluid media delivery means includes a centrifugal pump.
- 5. A system according to Claim 1 wherein said fluid media delivery means includes a pulsatile pump.
- 5 6. A system according to Claim 1 wherein said oxygenation means includes a membrane oxygenator.
 - 7. A system according to Claim 1 wherein said system further includes portable energy storage and supply means.
- 8. A system according to Claim 7 wherein said system is self-contained and portable.
 - 9. A system according to Claim 1 further including a rechargeable power supply for powering the system.
- 10. A system according to Claim 1 wherein the harvested organ is selected from the group consisting of a heart, kidney, liver, pancreas, lung, small intestine, blood
 15 carrying vessel and myocutaneous free flap.
 - 11. A system according to Claim 10 wherein said organ is maintained in a functioning state during said preservation period.
 - 12. A system according to Claim 10 wherein said organ is a heart.
- 13. A system according to Claim 11 wherein said heart is maintained in a beating state.





-66-

- 14. A system according to Claim 1 wherein said containment means further includes:
 - (a) filters to remove particular matter from said fluid media; and
 - (b) a defoaming screen to remove bubbles from recirculating fluid media.
- 5 15. A system according to Claim 1 wherein said containment means is a soft shell bag.
 - 16. A system according to Claim 15 wherein said soft shell bag contains:
 - (a) at least one arterial fitting:
 - (b) at least one venous fitting;
- 10
- (c) an inner zip-lock closure;
- (d) an outer zip-lock closure;
- (e) a vent assembly extending from the inner region of said soft shell bag containing said organ to the outside of said soft shell bag; and
- (f) means for hanging said soft shell bag on a rigid supportive structure.

75 (17) 70 Al

An organ preservation solution for the preservation of a human or human-compatible harvested organ in a functioning state comprising:

- (1) a metabolizable carbolydrate;
- (2) sodium chloride;
- (3) potassium;
- 20
- (4) calcium;
- (5) magnesium;
- (6) bicarbonate ion;
- (7) epinephrin; and
- (8) adenosine;
- wherein said solution is substantially free of a non metabolizable impermeants; and further wherein said solution has a pH of about 7.4 to about 8.5.

lati

18.

A solution according to Claim 17 wherein said solution further comprises a pharmaceutically active agent selected from the group consisting of heparin, nitroglycerin, an ACE inhibitor, a beta blocker, a calcium channel blocker, a cytoprotective agent, an antioxidant, an anti-fungal agnt, an anti-viral agent, an anti-bacterial agent, an immunosuppressive agent, a nonsteroidal anti-inflammatory agent, a steroid, vitamins and mixtures thereof.

19. A solution according to Claim 18 wherein said solution further includes and insulin.

10 20. A solution according to Claim 18 wherein said solution further includes a complement neutralizer.

21 21 21

A solution according to Claim 18 wherein said metabolizable carbohydrate is selected from the group consisting of dextrose, glucose, and mixtures thereof.

A solution according to Claim 18 wherein said solution further includes at least one fatty acid.

(00 22

15

23.

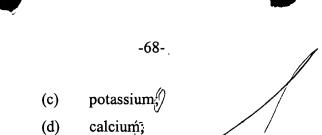
A method of preserving a human or human compatible harvested organ in a functioning state during a preservation period prior to implantation comprising:

- (a) providing an organ in need of preservation;
- (b) providing containment means for said organ;
- (c) providing a preservation fluid media; said fluid media comprising:
 - (i) whole blood or leukocyte-depleted whole blood that is compatible with said organ; and
 - (ii) a preservation solution comprising:
 - (a) a metabolizable carbohydrate;
 - (b) sodium chloride;

25

20

7



Cunt A3

5

10

15

25

25.

- (e) magnesium;
- (f) bicarbonate; epinephrin; and insulin;

(d) delivering said fluid media to at least one major vessel of said contained functioning organ while said organ is maintained at a normothermic temperature of about 20°C. to about 37°C.

24. A method according to Claim 23 wherein said media includes heparin.

A method according to Claim 23 wherein said media further includes a pharmaceutically active agent selected from the group consisting of nitroglycerin, an ACE inhibitor, a beta blocker, a calcium channel blocker, a cytoprotective agent, an antioxidant, an anti-fungal agnt, an anti-viral agent, an anti-bacterial agent, an immunosuppressive agent, a nonsteroidal anti-inflammatory agent, a steroid, and mixtures thereof.

- 26. A method according to Claim 23 wherein said media further includes at least one fatty acid.
- 20 27. A method according to Claim 26 wherein said method includes the further step of delivering said fluid media to the exterior of said organ.
 - 28. A method according to Claim 23 wherein said method includes the further step of filtering said fluid media as metabolic products from said organ accumulate in said fluid media.
 - 29. A method according to Claim 23 wherein said method includes the further step of oxygenation at least a part of said fluid media.

- 30. A method according to Claim 23 wherein said method comprises the further step of measuring the flow of said fluid media.
- 5 31. A method according to Claim 23 wherein said method comprises the further step of measuring the pressure of said fluid media.
 - 32. A method according to Claim 23 wherein the harvested organ is selected from the group consisting of heart, kidney, liver, lung, pancreas, small intestine, blood carrying vessel, and myocutaneous free flap.
- 10 33. A method according to Claim 32 wherein the organ preserved is a heart.

WAS